

EXHIBIT 5

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April 14, 2015

Via Email Only: David.Glass@usdoj.gov
David Glass, Esq.
US Department of Justice

RE: NECC Meningitis Litigation

Dear Mr. Glass,

I write to confirm the substance of our phone conference today regarding the FDA's objection to the subpoena and Notice of 30(b)(6) Deposition and *duces tecum* we issued to the FDA on March 6, 2015.

Based on the content of our discussion, we plan to file a motion to compel compliance with the subpoena later today. We will serve you with a copy of the motion by fax and email.

I attach two (2) orders previously entered in this litigation for your review. The first is a protective order entered in this litigation.¹ The FDA objected to producing documents that may contain trade secrets without a protective order in place. The protective order may resolve this objection.

The second order is an order entered by Magistrate Judge Boal on November 13, 2013, ruling on motions to quash several subpoenas issued in this litigation.² Magistrate Judge Boal has already ruled on many of the specific objections you raise, including:

1. Whether the MDL Court had the authority to issue the subpoena.
2. Whether we provided sufficient time to respond to the subpoena.
3. Whether the subpoena is overbroad and/or unduly burdensome.
4. Your confidentiality and privilege objections.

Her order may resolve some of your objections. Your objections are discussed further below.

¹ Dkt. 572.

² Dkt. 814.

I. Jurisdictional Objection

You objected to the subpoena because it was issued by the United States District Court for the District of Massachusetts. You asserted that the District of Massachusetts lacks personal jurisdiction over the FDA and that the subpoena should have been issued by the United States District Court for the District of Maryland.

However, as the transferee court in this multidistrict litigation, the District Court for the District of Massachusetts clearly has jurisdiction. 28 U.S.C. § 1407(b) expressly empowers an MDL court to “exercise the powers of a district judge in any district for the purpose of conducting pretrial depositions[.]” 28 U.S.C. § 1407(b) (emphasis added); see also *U.S. ex rel. Pogue v. Diabetes Treatment Centers of America, Inc.*, 444 F.3d 462, 468-69 (6th Cir. 2006) (describing MDL Court’s broad powers over nonparty discovery and noting that “the MDL judge is acting as a judge of the deposition or discovery district when he uses the authority outlined in Section 1407(b)”).

Again, Magistrate Judge Boal’s order may resolve this objection.

II. Objection to Producing a 30(b)(6) Designee for Deposition Testimony

Based on your representation of both the FDA and the United States Attorney’s Office prosecuting the NECC owners and employees, you categorically objected to producing a 30(b)(6) designee for deposition testimony.

You also objected to producing a witness on the grounds that the subpoena is overbroad and unduly burdensome. Without having read the complaint against our clients, you concluded that several of the requested topics for deposition testimony are irrelevant or have been answered by FDA Commissioner Hamburg’s Congressional testimony. Most of the topics in our notice are not addressed at all by Commissioner Hamburg’s testimony, such as the specific information the FDA made publicly-available regarding NECC prior to the outbreak. And, the remaining topics were addressed in only cursory fashion. Furthermore, we made clear that to the extent the requested documents are publicly available or were previously produced, you could state that is the case.

We are at an impasse on this issue.

III. Objection to Producing Documents

You reiterated the FDA’s objection to producing requested documents on the grounds that the subpoena is overbroad and unduly burdensome. However, the government must comply with reasonable requests for production, even when such requests “entail significant effort on the part of the United States.”³

³ *United States v. Magnesium Corp. of Am.*, No. 2:01-CV-40DB, 2006 U.S. Dist Lexis 87734 (D. Utah Nov. 27, 2006), at *15-16.

You also suggested that Commissioner Hamburg's testimony before Congress addressed much of the information contained in the documents requested in our *duces tecum*. This is simply false.

It is clear from the Congressional report titled "FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?" that (1) "the FDA produced only a limited number of documents...prior to the November 2012 hearing" and (2) the FDA has since produced a substantial number of additional documents to Congress.⁴ Accordingly, it would have been impossible for members of Congress to elicit testimony from Commissioner Hamburg regarding documents that had not yet been produced. It is also clear from the report that many of the documents produced to Congress have not been produced to us, such as internal FDA communications.

Finally, you objected to our subpoena as not providing adequate time to respond. We disagree. First, the FDA has been in the process of collecting, reviewing, and redacting documents pertinent to the outbreak since they were requested by Congress before the November 2012 Congressional hearing. Second, the Deposition Protocol governing these cases (which we sent with the subpoena) requires 30-days notice prior to taking a Rule 30(b)(6) deposition. We provided nearly double the required time by providing notice on March 6, 2015, for a deposition tentatively scheduled for May 4, 2015. We believe this is a reasonable amount of time to produce the documents we have requested.

I confirm that we initially reached out to the FDA in February to attempt to find a mutually-agreeable date. As we told the FDA roughly two months ago before we served the subpoena, we are willing to work with you to find a date we can all agree on, but we are dealing with a mid-June discovery deadline. Please let us know how much time you need to produce the requested documents.

IV. Motion to Compel

At the conclusion of our phone conference, you stated that the FDA will file a motion to quash the subpoena if we do not narrow our requests. Given the mid-June discovery deadline, we plan to expedite the process by filing a motion to compel today. We will serve you with a copy of the motion today via email and fax. Under the Local Rules for the United States District Court for the District of Massachusetts, your response will be due by April 28.⁵

We intend to request that Magistrate Judge Boal hear argument on the motion at the hearing she currently has scheduled for these cases on April 29, 2015 at 11:30 a.m. in Courtroom 14 of the Federal Courthouse in Boston, Massachusetts.

⁴ The Congressional report is attached. See pp. 1-2.

⁵ See Local Rule 37.1(c).

We are happy to continue to work toward resolving your objections between now and the April 29 hearing once you have had a chance to review this letter and the attached orders.

Sincerely,



Jeremy C. Cain

JCC/jkl